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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,124	10/09/1997	ELLIS REINHERZ	DFCI-522A	6658

21005 7590 01/26/2006

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/948,124	<b>Applicant(s)</b> REINHERZ ET AL.	
	<b>Examiner</b> Christopher H. Yaen	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41,64,66,68-71 and 4563 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41,63,64 and 66 is/are allowed.
- 6) ☐ Claim(s) 45 and 68-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

**RE: REINHERZ et al**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The amendment filed 10/19/2005 is hereby acknowledged and entered into the record. Accordingly, claims 1-40,42-44,46-62,65, and 67 are canceled without prejudice or disclaimer.
3. Claims 41,45,63-64,66, and 68-71 are pending and examined on the merits.

***Claim Rejections Withdrawn - 35 U.S.C. § 112 1<sup>st</sup> paragraph***

4. The rejection of claims 41,45,63-64,66, and 68-71 under 35 USC § 112, 1<sup>st</sup> paragraph lacking an enabling disclosure is withdrawn in view of the persuasive arguments set forth by the applicant in the paper filed 10/19/2005.

***Claim Rejections Withdrawn - 35 U.S.C. § 112 1<sup>st</sup> paragraph***

5. The rejection of claims 41,45,63-64,66, and 68-71 under 35 USC § 112, 1<sup>st</sup> paragraph as lacking adequate written description is withdrawn in view of the persuasive arguments set forth by the applicant in the paper filed 10/19/2005.

***New Arguments***

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

6. Claims 45, and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The claims recite an "agent" as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature that provides the recited function of an agent capable of enhancing the activity of a caspase or procaspase, as claimed. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3<sup>rd</sup> column).

Applicant does not appear to have reduced to practice any caspase or procaspase agonists as claimed. There is no evidence that there is any structural-functional relationship established for the claimed agonists and any other that might be found using the claimed methodology provided in the specification. Moreover, structural characteristics of the genus of agonists or agents claimed have not been disclosed, nor is there a description of other identifying characteristics that embody the genus of

agents such that one of skill in the art can readily envisage in clear, concise, and exact terms such that the artisan can recognize that applicant was in possession of the broad recitation of agents claimed. An "agent" encompasses *any* molecule with the functional activity of enhancing the activity of caspase or procaspase. The specification indicates that such agents encompass "compounds or enzymes which will convert procaspase to caspase, enhance oligomerization of the caspase, or an enzymatically active fragment or variant thereof, a sequence which encodes one of the above in an appropriate expression vector or a compound which will enhance the expression of the procaspase or caspase in the cell" (see page 38-39). However, the specification does not provide any starting point from which one of skill in the art can begin to search for such "agents". Thus the genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id. While it is noted that the

instant claims are drawn to methods, the claims nevertheless require an adequate written description of the caspase or procaspase enhancing "agents" employed in the methods.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

### ***Conclusion***

Claims 41,63-64, and 66 appear to be free of the prior art. Claims 45, and 68-71 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1643  
January 22, 2006

  
**CHRISTOPHER YAEN**  
**PATENT EXAMINER**